In re Application of: HAREL et al

Serial No.: 10/526,708 Filed: September 25, 2007

Office Action Mailing Date: July 19, 2007

Examiner: FLORY F.A Group Art Unit: 3762 Attorney Docket: 34490

In the Claims:

1. (Original) A method of glucose level control, comprising:

providing at least one electrode adapted to apply an electric field to a pancreas; and

applying an electric field to the pancreas using said at least one electrode such that blood glucose levels are significantly reduced and blood insulin levels are not significantly increased.

- 2. (Original) A method according to claim 1, comprising subsequently applying a second electric field to said pancreas, which second field increases insulin levels.
- 3. (Original) A method according to claim 1, wherein said electric field is operative to reduce glucagon secretion.
- 4. (Original) A method according to claim 1, wherein said electric field is operative to reduce glucose secretion by a liver physiologically coupled to said pancreas.
- 5. (Original) A method according to claim 1, wherein said electric field is operative to increase glucose uptake by cells in a body containing said pancreas.
- 6. (Original) A method according to claim 1, wherein said electric field is operative to affect nervous tissue in said pancreas.

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- 7. (Original) A method according to claim 1, wherein said electric field is non-excitatory in that it does not substantially induce new bursts of islet activity in said pancreas.
- 8. (Original) A method according to claim 1, wherein said electric field is applied as a bi-phasic and charge balanced time varying field.
- 9. (Original) A method according to claim 8, wherein said electric field is applied for a short duration every period of time.
- 10. (Original) A method according to claim 9, wherein said period of time gives an application frequency of between 1Hz and 15 Hz.
- 11. (Original) A method according to claim 9, wherein said period of time gives an application frequency of about 5 Hz.
- 12. (Original) A method according to claim 9, wherein said duration is less than 30 ms.
- 13. (Original) A method according to claim 9, wherein said duration is about 10 ms.
- 14. (Original) A method according to claim 1, wherein said electric field is repeated for a period of less than 30 minutes.

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- 15. (Original) A method according to claim 1, wherein said electric field is repeated for a period of between 30 and 180 minutes.
- 16. (Original) A method according to claim 1, wherein said electric field is applied for substantially all of a duration of a glucose absorption event.
- 17. (Original) A method according to claim 1, wherein said electric field is applied prior to an expected glucose ingestion event.
- 18. (Original) A method according to claim 1, comprising triggering said electric field by a glucose ingestion event.
- 19. (Original) A method according to claim 1, wherein said electric field is applied irrespectively of an ingestion event.
- 20. (Original) A method according to claim 1, wherein said electric field is applied at least part of the time irrespective of a blood glucose level
- 21. (Original) A method according to claim 1, wherein said electric field is applied continuously for at least 24 hours.
- 22. (Original) A method according to claim 1, wherein said electric field is applied for a period of at least 15 minutes without sensing of its effect.

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- 23. (Original) A method according to claim 1, wherein said electric field is of a magnitude and temporal extent so that it does not significantly change blood insulin and glucose levels in the absence of an ingestion event.
- 24. (Original) A method according to claim 1, wherein said electric field reduces blood glucose levels by at least 20% of an elevation of the glucose level above a fasting baseline glucose level.
- 25. (Original) A method according to claim 1, wherein said electric field does not increase blood insulin levels, as measured by an average over five minutes, by more than 20%.
- 26. (Original) A method according to claim 1, comprising, delaying a gastric emptying by applying a treatment to the stomach.
- 27. (Original) A method according to claim 1, wherein said electric field is operative to delay a glucose peak at least by a duration of its application.
- 28. (Original) A method according to claim 1, wherein said electric field is operative to delay a glucose peak at least by 10 minutes.
- 29. (Original) A method according to claim 1, wherein said electric field is operative to delay an insulin peak at least by 10 minutes.

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30. (Original) A method of glucose level control, comprising:

providing at least one electrode adapted to apply an electric field to a pancreas; and

applying an electric field to the pancreas operative to reduce blood glucose levels if elevated and not significantly reduce such levels if not substantially elevated.

- 31. (Original) A method according to claim 30, wherein said electric field reduces elevated glucose levels by at least 20%.
- 32. (Original) A method according to claim 30, wherein said electric field does not reduce unelevated glucose levels by more than 10%
- 33. (Original) A method according to claim 30, wherein said electric field does not impair exocrine functions of said pancreas.
- 34. (Currently amended) Apparatus for blood glucose control, comprising:
 at least one electrode adapted to apply an electric field to a pancreas; and
 circuitry adapted to electrify said at least one electrode and configured to
 electrify said electrode in a manner which compensates for a loss of acute response by
 said pancreas, wherein said circuitry reduces or prevents a substantial increase in
 insulin secretion during said compensation.
- 35. (Original) Apparatus according to claim 34, wherein said circuitry compensates by causing the secretion of an insulin bolus.

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- 36. (Original) Apparatus according to claim 34, wherein said circuitry compensates by reducing glucose levels in a non-insulin manner.
- 37. (Original) Apparatus according to claim 36, wherein said circuitry compensates by reducing glucagon secretion.
- 38. (Cancelled)
- 39. (Original) Apparatus according to claim 34, wherein for at least 20% of ingestion events said circuitry applies only an acute control of insulin levels.
- 40. (Original) Apparatus according to claim 39, wherein said apparatus is programmed with a knowledge of a slow acting chemical-based insulin therapy provided to said pancreas.
- 41. (Original) Apparatus according to claim 34, comprising an automatic ingestion sensor for automatically detecting an ingestion event.
- 42. (Original) Apparatus according to claim 34, comprising an automatic glucose sensor for automatically detecting a situation requiring an acute response.
- 43. (Original) Apparatus according to claim 34, comprising an automatic glucose sensor for automatically detecting a situation requiring an acute insulin response.

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44. (Original) Apparatus according to claim 34, wherein said response is an acute insulin response.

45 - 48. (Cancelled)

49. (Original) Apparatus for blood glucose control, comprising:

at least electrode adapted to apply an electric field to pancreatic tissue; and circuitry adapted to electrify said at least one electrode and configured to electrify said electrode in a manner which reduces glucose levels and does not substantially elevate insulin levels above a baseline value, when glucose levels are elevated.

- 50. (Original) Apparatus according to claim 49, wherein said circuitry is a closed loop system including sensing of the effect of the electrification and wherein said circuitry is configured to over stimulate in cases of doubt.
- 51. (Original) Apparatus according to claim 49, wherein said circuitry is a semi-open loop system where a relatively long stimulation series is applied without feedback.
- 52. (Original) Apparatus according to claim 49, wherein said circuitry is an open loop system where a stimulation series is applied responsive to a trigger and without feedback.
- 53. (Original) Apparatus according to claim 49, wherein said circuitry applies a constant voltage field.

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- 54. (Original) Apparatus according to claim 49, wherein said circuitry applies a constant current field.
- 55. (Original) Apparatus according to claim 49, wherein said pancreatic tissue comprises an in-vivo pancreas.
- 56. (Original) Apparatus according to claim 49, wherein said pancreatic tissue comprises a pancreatic tissue implant.
- 57. (New) A method of controlling blood glucose after an ingestion event, the method comprising:

providing at least one electrode;

identifying an ingestion event; and

after said identifying, electrifying said at least one electrode to apply electric field to a pancreas, in a manner which applies only acute control of insulin.

- 58. (New) A method according to claim 57, wherein said electrifying is in accordance with a fixed protocol.
- 59. (New) A method according to claim 58, wherein said fixed protocol is configured for treating a specific patient.
- 60. (New) A method according to claim 58, wherein said fixed protocol is configured for treating a specific disease state.

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61. (New) A method of controlling blood glucose, the method comprising:

providing at least one electrode;

providing a fixed protocol; and

electrifying said at least one electrode to apply electric field to a pancreas in accordance with said fixed protocol,

wherein said electrifying comprises electrifying irrespective of blood glucose level.

- 62. (New) A method according to claim 58, wherein said fixed protocol comprises electrifying said at least one electrode to provide a pulse series without synchronizing said pulse series to pancreatic activity.
- 63. (New) A method according to claim 58, wherein said fixed protocol comprises electrifying said at least one electrode to provide a pulse series irrespectively of an ingestion event.
- 64. (New) A method according to claim 58, wherein pancreatic electrical activity is not measured during said electrifying.
- 65. (New) A method according to claim 58, wherein said fixed protocol comprises periodic application of a pulse series.
- 66. (New) A method according to claim 58, wherein said electric field is repeated for a period of less than 30 minutes.
- 67. (New) A method according to claim 58, wherein said electric field is repeated for a period of between 30 and 180 minutes.